

**REMARKS**

**STATUS OF THE CLAIMS**

Claims 1-33 are pending. No claim amendments have been made and no new matter has been added.

**FORMAL MATTERS**

As requested by the Examiner, attached is a copy of the Information Disclosure Statement and Form PTO-1449 filed on December 14, 2001. (Office Action dated May 21, 2003, at 7.) Also, attached is a copy of the date stamped postcard. Applicant respectfully requests that the Examiner initial the copy of the 1449 form and return it to Applicant as acknowledgement that the disclosed references were considered.

**REJECTION UNDER 35 U.S.C. §103**

The Examiner rejects claims 1-33 under 35 U.S.C. § 103(a) over WO 98/33494 ("Kosbab") in view of U.S. Patent No. 6,248,375 B1 ("Gilles") and further in view of U.S. Publication No. 2002/0025034A1 ("Arbiser"). *Id.* at 2. Applicant respectfully traverses the rejection for the reasons already of record as well as those presented below.

In order to establish a prima facie case of obviousness, the Examiner must establish that the references, alone or in combination, teach or suggest all the claim elements. M.P.E.P. § 2143 (8<sup>th</sup> ed. 2001).

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
www.finnegan.com

**1. Independent Claims 1 And 22 Are Patentable  
Over The Cited References**

The composition of claims 1 and 22 and the claims dependent from them require the presence of 4 to 6 grams of insulin and 4 to 6 grams of FOS.

As noted by the Examiner, Kosbab teaches that in preferred compositions its disclosed "components are combined with components that regulate glucose or insulin levels." Page 4, lines 5-6, and Office Action dated October 22, 2002, at 2. The Examiner has not pointed to a teaching or suggestion in Kosbab, and Applicant does not believe that such a teaching or suggestion exists, that insulin, as a component itself, may be added to its composition. More specifically, the Examiner has not pointed to a teaching or suggestion in Kosbab of a composition comprising from 4 to 6 g insulin, as presently recited in independent claims 1 and 22 and dependent claims 2-5 and 7-10.

The Examiner attempts to rely on Gilles to overcome these deficiencies of Kosbab. Gilles teaches that a primary treatment for glucose intolerance is strict adherence to diet and "in many cases, use of medications (insulin or oral hypoglycemic agents)." Col. 1, lines 24-27, and referred to by the Examiner in the Office Action dated May 21, 2003, at 4. However, the Examiner has not pointed to a teaching or suggestion in Gilles, and Applicant does not believe that such a teaching or suggestion exists, that insulin, as a component itself, may be added to the nutritional matrices that Gilles describes and claims. More specifically, the Examiner has not pointed to a teaching or suggestion in Gilles of a composition comprising from 4 to 6 g insulin, as presently recited in independent claims 1 and 22.

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FARABOW  
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DUNNER LLP

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The Examiner also acknowledges that Kosbab does not teach FOS. Office action at page 3, lines 15-17. While Gilles does disclose the use of FOS in his nutritional bars, the amount of FOS is 3.5 to 5 times greater than the amount used in the claimed invention. See Tables 5 and 6 of Gilles, where the amount of FOS is 21.2 grams. There is no teaching or suggestion in Gilles to use FOS in the amount of 4 to 6 grams.

The newly cited reference, Arbiser, does not teach or suggest a composition comprising 4 to 6 g insulin or 4 to 6 g of FOS as components of the composition.

Although the Examiner has found reference to insulin in two of the three cited references, the tangential teachings of insulin in these references as a treatment for diabetes does not constitute the objective teaching required to establish a prima facie case of obviousness. Gilles distinguishes at Col. 3, lines 23-26, between diet and medication in the treatment of glucose intolerance and mentions insulin only as a medication. Gilles does not teach or suggest that the insulin should be added to its solid matrix materials, in the form of food products. Moreover, Applicant respectfully submits that Gilles distinction between "insulin or oral hypoglycemic agents" would indicate to one of skill in the art that the insulin is not administered orally. Therefore, Gilles would teach away from use of oral insulin in a composition. And certainly Gilles does not teach or suggest a composition comprising 4 to 6 grams of insulin.

For at least these reasons, independent claims 1 and 22 and the claims dependent from them are patentable over the cited references.

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HENDERSON  
FARABOW  
GARRETT &  
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**2. Independent Claims 1, 6, 11, 17, 22 and 29 Ar  
Patentabl Over The Cited References**

The Examiner admits that one of the differences between the primary reference and Applicant's claimed invention is the specific dosage range set forth in claims 1, 6, 11, 17, 22 and 29. Office action at 3. The Examiner asserts that the amounts of the active agents to be used are within the knowledge of the skilled pharmacologist and the broad range of usual amounts taught by Kosbab. Applicant disagrees.

Without acquiescing in whether the broad ranges of daily dosages recited for individual compounds in Table 3 of Kosbab are particularly relevant to specific compositions made up of several compounds, it is noteworthy that Kosbab either omits certain of the required compounds of the claimed compositions or recites them in a dosage that is outside that required by the present claims.

For example, the Examiner has failed to point to any teaching or suggestion in Kosbab of a composition comprising 15 mg niacin, as presently recited in independent claims 1, 6, 11, 17, 22, and 29.

Gilles does not overcome the deficiency of Kosbab. Gilles teaches that a vitamin and mineral system for a solid matrix nutritional supplement comprises "at least 10% of the RDI, preferably at least 15% of the RDI " of niacin. Col. 11, lines 1-5. Gilles does not teach or suggest the RDI amount for niacin. Moreover, Gilles does not teach or suggest the amount of the vitamin mineral system used in the solid matrix nutritional supplement. The Examiner has failed to point to any teaching or suggestion in Gilles of a composition comprising 15 mg niacin, as presently recited in independent claims 1, 6, 11, 17, 22, and 29.

The Examiner relies on Arbiser for teaching curcuminoids and does not point to any teaching or suggestion in Arbiser of a composition comprising 15 mg niacin as a component of the composition.

Similarly, instant claims 1, 6, 11, 17, and 22 require 200 mcg of Vitamin K. The dosage range for Vitamin K at page 49 of Kosbab is 15-75 mcg. Gilles mentions a dose of 19.8 mcg in Tables 5 and 6. Arbiser is silent on Vitamin K.

Claims 1, 6, 11, 17, 22, and 29 all require 100 mcg of zeaxanthin. The dosage range for this same antioxidant at page 47 of Kosbab is 1-300 mg. Gilles and Arbiser are silent on zeaxanthin.

Claims 1, 6, 11, 17, 22, and 29 all require 200 mcg of biotin. Table 3 of Kosbab does not give a dosage range for biotin and the single mention of biotin in Kosbab at page 13, line 12 is without an amount. Gilles at Tables 5 and 6 mentions 74.65 mg of biotin. Arbiser is silent on biotin.

The specific claimed amounts of at least insulin, FOS, niacin, vitamin K, zeaxanthin and biotin are claim elements which are missing from Kosbab and are not found in Gilles or Arbiser. Therefore, for at least these reasons, independent claims 1, 6, 11, 17, 22 and 29 and all claims dependent from them are patentable over the cited references.

Applicant respectfully submits that the Examiner has failed to establish a prima facie case of obviousness. Reconsideration and withdrawal of the rejection are respectfully requested.

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HENDERSON  
FARABOW  
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**CONCLUSION**

In view of the foregoing remarks, Applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims 1-33.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

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By: Carol L. Cole  
Carol L. Cole  
Reg. No. 43,555

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
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